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Attorneys for Plaintiff
ORGANOGENESIS, INC.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ORGANOGENESIS, INC.,

Plaintiff,

-against-

ADVANCED BIOHEALING, INC.,

Defendant.

Civil Action No. 08 CV 00875 (AKH

Declaration of Patrick Bilbo in Support of Motion for Temporary Restraining Order and Motion for Preliminary Injunction

I, Patrick Bilbo, do hereby declare as follows:

1. I am the Vice President, Regulatory Affairs of Organogenesis, Inc. I am authorized to make this declaration on behalf of Organogenesis, Inc. ("OI"). I am over eighteen years of age.

2. I have personal knowledge of the facts set forth herein, except for those stated to be upon information and belief, and if called as a witness, would and could competently testify thereto under oath.

APLIGRAF

3. OI was founded in 1985. OI is a pioneer in the field of regenerative medicine and is a leading regenerative medicine company. It researches, develops, and commercializes regenerative medicine technologies to deliver living, cell-based products to stimulate the body's natural healing process and activate the body's ability to repair and regenerate.

4. OI is the manufacturer, distributor, and owner of all rights in Apligraf® ("Apligraf"). Apligraf is biological tissue derived from human skin cells that, similar to human skin, contains two types of cells – an outer layer of protective skin cells (epidermal cells), and an inner layer of cells (dermal cells), both of which contain proteins and other substances that initiate the healing process. Apligraf is able to help heal and repair chronic sores and regenerate skin by stimulating the body's healing process. It delivers these biological healing substances (living cells and active proteins) directly into the wound thereby starting the healing cycle.

5. After years of research and development, in 1998, OI received the first ever Food and Drug Administration ("FDA") approval for a manufactured living cell-based therapy, Apligraf, intended for the treatment of venous leg ulcers. In 2000, FDA approved Apligraf for the treatment of diabetic foot ulcers. Currently, Apligraf is the only bio-active product that is approved by the FDA to treat both chronic diabetic foot ulcers and venous leg ulcers.

6. Diabetic foot ulcers and venous leg ulcers are conditions that often affect the elderly, Type II diabetics, or patients suffering from peripheral vascular disease. Apligraf has been hailed a miracle of science and has changed the lives of patients suffering from such chronic skin ulcers. Prior to Apligraf, skin ulcers that would not respond to traditional wound treatment would often progress to a limb amputation or life threatening condition. Apligraf has not only helped improve a patient's quality of life, but in many cases, it has saved a patient who otherwise may have lost a limb or succumbed to a life-threatening infection.

7. Apligraf is a prescription product that must be applied directly to a wound by a medical professional. OI has invested significant resources towards building a highly skilled sales and marketing organization dedicated to Apligraf. Copies of marketing materials regarding

Apligraf are attached as Exhibit 1. To date, over 200,000 units of Apligraf have been applied to patients.

8. Apligraf customers primarily consist of physicians, podiatrists, hospitals, and wound care treatment centers and clinics.

THE APLIGRAF RECALL

9. In December 2007, OI learned that two packaging lots of Apligraf containing a total of 177 distributed Apligraf units were potentially contaminated (the "Affected Apligraf Units").

10. Upon learning of the potential contamination, OI promptly designed and implemented a recall procedure for the Affected Apligraf Units in consultation with the FDA (the "Apligraf Recall").

11. In conducting the Apligraf Recall, OI identified all customers who had received the Affected Apligraf Units. OI then contacted only those customers who received the Affected Apligraf Units to ensure OI's ability to properly and effectively track the Apligraf Recall. Conducting a targeted recall also facilitates OI's ability to assist its Apligraf customers in monitoring the impact of any Affected Apligraf Units that may have been administered to patients.

12. OI sent a letter to each of its customers who had received the Affected Apligraf Units (the "Apligraf Recall Letter"). The Apligraf Recall Letter discloses the reason and clinical implications for the Apligraf Recall, provides contact information in the event of questions, and requests that the recipient provide OI with written confirmation of receipt of the Apligraf Recall Letter. A copy of the Apligraf Recall Letter is attached hereto as Exhibit 2.

13. Indeed, the Apligraf Recall Letter makes it clear that it is *only* being sent to an Apligraf customer who received the Affected Apligraf Units. *See* Exhibit 2.

14. The Apligraf Recall Letter further advises Apligraf customers who received the Affected Apligraf Units regarding the clinical implications of the Apligraf Recall:

> While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. **Treatment options at your discretion include topical antibiotics, oral antibiotics or Apligraf removal.** We hope that this information is helpful in managing care for your patient.

Exhibit 2 at pp. 1-2 (Emphasis Added).

ADVANCED BIOHEALING'S FALSE AND MISLEADING ADVERTISEMENTS

15. Defendant Advanced BioHealing, Inc. ("Advanced BioHealing"), which upon information and belief was recently founded in 2003, is a direct competitor of OI's Apligraf product. Upon information and belief, Advanced BioHealing distributes and sells Dermagraft® ("Dermagraft"), a product used for the treatment of wounds such as certain diabetic foot ulcers and wounds associated with dystrophic epidermolysis bullosa. Upon information and belief, Dermagraft is not FDA approved for the treatment of venous leg ulcers.

16. On or about January 8, 2008, Advanced BioHealing sent out an electronic mail communication to at least one physician in the New York area. A copy of the electronic mail message is attached as Exhibit 3.

17. The electronic mail communication (the "Advanced BioHealing Communication"), which was sent by Advanced BioHealing to wound care providers states:

Wound Care Provider,

I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.

A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.

Proprietary cryopreservation process ensures confidence
Dermagraft is cryopreserved to allow long-term maintenance of tissue integrity and cellular viability. Cryopreservation of Dermagraft offers a number of additional product benefits:

- Allows for safety testing prior to shipping and application
- Provides longer shelf life—long-term storage (up to 6 months) when stored at -75°C ± 10°C

There have been no reported immunological responses or rejections from patients that received Dermagraft.

Andrew Sole
Advanced Technolgy Specialist-New York
Advanced BioHealing, Inc.
Direct: 732 991-3610
Email: <mailto:lmyers@advancedbiohealing.com> asole@advancedbiohealing.com
Orders: 1-877-DERMAGRAFT (877-337-6247)

18. OI obtained a copy of the Advanced BioHealing Communication from two physicians located in New York on or about January 9, 2008.

19. Upon information and belief, Advanced BioHealing also sent out the Advanced BioHealing Communication to physicians and other wound care professionals by electronic mail message, facsimile or other means throughout the United States including, including, but not limited to, Florida, Michigan, New York, and Virginia.

20. Upon information and belief, in addition to circulating the Advanced BioHealing Communication by electronic mail message, Advanced BioHealing has also sent its

representatives to a number of wound care treatment centers to disseminate the Advanced BioHealing Communication in person to physicians and nurses.

21. Additionally, Apligraf customers have reported to OI that Advanced BioHealing sales representatives have made various oral statements to Apligraf customers consistent with the Advanced BioHealing Communication.

22. Upon learning of the Advanced BioHealing Communication, OI immediately advised Advanced BioHealing of the false claims contained in the Advanced BioHealing Communication and requested that Advanced BioHealing stop further dissemination of the Advanced BioHealing Communication. A copy of OI's request is attached hereto as Exhibit 4.

23. Initially, Advanced BioHealing stated that it would investigate OI's claims. A copy of Advanced BioHealing's response is attached hereto as Exhibit 5.

24. Later, on or about January 14, 2008, Advanced BioHealing indicated that it had ceased disseminating communications regarding the Apligraf Recall as of January 9 or 10, 2008, and would continue to do so while the parties' discussed the possibility of settlement.

ADVANCED BIOHEALING CONTINUES AND ESCALATES ITS WRONGFUL CONDUCT

25. On or about January 16, 2008, OI learned that Advanced BioHealing may not have ceased disseminating communications regarding the Apligraf Recall.

26. More specifically, OI received an electronic mail message from one of its customers that appeared to indicate that an Advanced BioHealing employee, Carol Gray, was attempting to recall an electronic mail message on January 14, 2008.

27. OI promptly contacted Advanced BioHealing through counsel. A copy of OI's correspondence to Advanced BioHealing's counsel is attached as Exhibit 6.

28. In response, Advanced BioHealing *now* assured OI, in writing, that it notified its sales force to ceased sending communications regarding the Apligraf Recall as of January 11, 2008. A copy of Advanced BioHealing's correspondence from counsel is attached as Exhibit 7.

29. On January 18, 2008, OI learned definitively that Advanced BioHealing had not ceased disseminating communications regarding the Apligraf Recall as of January 9, 10 or 11, 2008 despite Advanced BioHealing's representations to the contrary.

30. Indeed, OI learned that on or about January 14, 2008, Advanced BioHealing sent out another electronic mail communication to OI's customers and other wound-care providers (the "Additional Advanced BioHealing Communication"). A copy of the electronic mail message is attached as Exhibit 8.

31. The Additional Advanced BioHealing Communication contained the subject line "Copy of the Recent Apligraf Recall Letter, Unparalled [sic] Safety Profile of Dermagraft" and stated as follows:

Keeping You Informed:

Attached is the letter announcing the recent Apligraf recall from Organogenesis. Apligraf recalls have happened many times. (as reported to the FDA and documented on the FDA website).

Dermagraft has an unparalleled safety profile:

Advanced Biohealing, Inc. will not send any Dermagraft to customers, for use on their patients, until the End of Production- USP Sterility Data Testing Results are completed (conducted by an independent laboratory):

~end of production USP Sterility Safety testing is a requirement *before* patient application with Dermagraft. Dermagraft has a 5 month shelf life.

~end of production USP Sterility Safety testing results for Apligraf are not obtained until *after* application to patients receiving Apligraf. This may put patients and their providers at risk.

Apply Dermagraft with confidence! Safety Unparalleled!

Carol Gray
Advanced Technology Specialist
Mobile: 443 306 4762
EMail: cgray@advancedbiohealing.com

32. OI obtained a copy of the Additional Advanced BioHealing Communication from one of its Apligraf customers.

ADVANCED BIOHEALING HAS INTERFERED WITH THE APLIGRAF RECALL THEREBY JEOPARDIZING PUBLIC HEALTH

33. Advanced BioHealing's actions have unnecessarily expanded the scope of the Apligraf Recall and interfered with the administration of the Apligraf Recall, thus jeopardizing public safety and health.

34. As discussed, OI has advised Apligraf physicians, who received the Affected Apligraf Units, regarding treatment options available to them including the administration of topical antibiotics, oral antibiotics or Apligraf removal. Apligraf removal involves subjecting a patient to an additional surgical procedure.

35. It is my understanding that at least one physician who received an Affected Apligraf Unit has opted to surgically remove the Apligraf unit. Surgical removal of an Apligraf unit involves debriding (*i.e.*, scraping) the Apligraf off the wound in a surgical, sterile operating field.

36. It is conceivable that other physicians who have erroneously received the Advanced BioHealing Communication and Additional Advanced BioHealing Communication may subject their patients to surgical removal of a **non**-Affected Apligraf Unit as a result of confusion stemming from the Advanced BioHealing Communication.

37. Further, Advanced BioHealing's conduct has unnecessarily expanded the scope of the Apligraf Recall from a relatively narrow recall of approximately 177 Apligraf units to

potentially thousands of Apligraf units. As a result, OI has had to devote its efforts to not only addressing inquires from customers who received the Affected Apligraf Units, but also fielding inquires and receipt forms from those Apligraf customers who did **not** receive the Affected Apligraf Units.

38. Advanced BioHealing's actions have resulted in numerous calls to OI's customer service and medical inquiries department by customers who are not affected by the Apligraf Recall. As a result, OI's ability to fully and accurately track and report with precision the effectiveness of the Apligraf Recall is hampered.

39. According to an Apligraf salesperson, the Advanced BioHealing Communication has also incited "panic" at one of her Apligraf customer's wound care treatment facilities.

40. Advanced BioHealing's actions have irreparably harmed OI in that Advanced BioHealing has caused widespread marketplace confusion regarding Apligraf and the Apligraf Recall.

41. Advanced BioHealing has also unnecessarily caused Apligraf customers to unnecessarily question whether they have received the Affected Apligraf Units creating the possibility that patients will needlessly be subjected to painful surgery or other unnecessary clinical treatment.

42. Advanced BioHealing's actions have also potentially damaged the Apligraf Brand.

THE ADVANCED BIOHEALING COMMUNICATION AND THE ADDITIONAL ADVANCED BIOHEALING COMMUNICATION HAVE CONFUSED AND DECEIVED APLIGRAF CUSTOMERS

43. Judging from the content of the Advanced BioHealing Communication and the Additional Advanced BioHealing Communication, the Advanced BioHealing Communication

and the Additional Advanced BioHealing Communication focus on current and potential Apligraf customers.

44. A number of Apligraf customers have contacted OI to inquire about whether they received the Affected Apligraf Units and to express concern and confusion as to whether their patients received the Affected Apligraf Units.

45. For example, after Advanced BioHealing disseminated the Advanced BioHealing Communication to nurses at a wound treatment center in New York, "panic" ensued as the nurses attempted to determine whether their patients were affected by the Apligraf Recall. It was reported to an OI Apligraf sales representative that the nurses were confused by the Advanced BioHealing Communication and concerned about the impact of the Apligraf Recall on their patients. They proceeded to "frantically" rifle through patient files to determine if they received the Affected Apligraf Units. The nurses were further concerned and confused as to why they had not received notification from OI regarding the Apligraf Recall.

46. Additionally, after receiving the Advanced BioHealing Communication, a number of Apligraf customers have contacted OI to (1) express confusion as whether they received the Affected Apligraf Units; (2) return Apligraf units that are not impacted by the Apligraf Recall; and (3) return written receipt of the Apligraf Recall Letter despite the fact that they did not receive Affected Apligraf Units.

47. Due to confusion associated with the Advanced BioHealing Communication, OI had to provide two of the largest national wound care chains, with hundreds of facilities across the United States, with clarification of the Apligraf Recall including a written summary of the Apligraf Recall, a summary of OI's actions with respect to the Apligraf Recall, and explanation of the relevance of the Advanced BioHealing Communication to the Apligraf Recall.

48. Upon information and belief, the Additional Advanced BioHealing Communication has also caused confusion among OI's customers and has damaged OI's relationships with consumers by suggesting that Apligraf is not safety-tested prior to distribution.

THE MISLEADING AND FALSE CLAIMS

The Advanced BioHealing Communication

49. The Advanced BioHealing Communication is false and misleading in that it purports to be a "safety notification."

50. The Advanced BioHealing Communication is misleading in that it implies that OI selectively and improperly sent out the Apligraf Recall Letter to only certain Apligraf customers. This claim is misleading because OI sent out the Apligraf Recall Letter to all Apligraf customers who received the affected Apligraf Units pursuant to an FDA approved recall protocol. Further, OI sent the Apligraf Letter directly to the treating physician who received the Affected Apligraf Unit to ensure the smooth administration of the Apligraf Recall and to minimize the possibility that multiple letters would be sent to multiple individuals within a wound care treatment practice.

51. The Advanced BioHealing Communication claims that "the advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves *no chance for contamination and 100% confidence in safety* for your patients' wounds." (Emphasis Added). Exhibit 2. This claim is false because Dermagraft and a related product Dermagraft-TC underwent a recall in 1998 for endotoxin levels that did not meet FDA standards and a 2003 recall for distributed product that did not meet specifications. *See* FDA Enforcement Report dated May 20, 1998 for Dermagraft attached as Exhibit 9. *See also* FDA Enforcement Report dated June 11, 2003 for Dermagraft attached as Exhibit 10.

52. Advanced BioHealing's claim that "Dermagraft goes through 14 day sterile testing by the FDA before it is shipped" is false because the FDA does not conduct sterility testing or any type of testing. The claims also imply that FDA is actively involved in the Dermagraft manufacturing process, and that Apligraf somehow fails to meet FDA standards. These claims are misleading and false in that OI has rigorous internal standards to ensure compliance with applicable FDA standards and regulations.

53. The Advanced BioHealing Communication claims that cryo-preservation of Dermagraft "allows for safety testing prior to shipping and application". This claim misleadingly implies that Apligraf is not safety tested prior to release.

The Additional Advanced BioHealing Communication

54. The Additional Advanced BioHealing Communication contains a number of misleading statements. For instance, the Additional Advanced BioHealing Communication misleadingly implies that Apligraf's safety record and/or safety protocol place wound care practitioners and patients at risk.

55. The Additional Advanced BioHealing Communication also misleadingly implies that Apligraf is not safety-tested until after it is applied to patients.

ADVANCED BIOHEALING HAS HARMED OI'S BUSINESS AND APLIGRAF

56. Advanced BioHealing actions have irreparably harmed OI.

57. Upon information and belief, Advanced BioHealing has misled some of OI's customers into believing that Apligraf is not properly tested.

58. Upon information and belief, Advanced BioHealing has led some Apligraf customers to mistrust OI in that OI's customers have questioned whether OI improperly failed to notify them of the Apligraf Recall.

59. OI has also received inquiries from its Apligraf customers suggesting that Advanced BioHealing's actions have led OI's customers to question whether OI improperly failed to notify them of the Apligraf Recall.

60. Advanced BioHealing's actions have also prompted Apligraf customers to unnecessarily question whether their patient's safety is impacted by the Apligraf Recall; thus increasing the likelihood that some patients may be needlessly exposed to unwarranted clinical treatment.

61. Advanced BioHealing's actions caused a strain on Apligraf's relationships with prospective customers and its valued, current customers, who have demonstrated loyalty to Apligraf. Advanced BioHealing's actions have also potentially harmed OI's Apligraf sales.

62. The full extent of the harm and damage caused by Advanced BioHealing's deceptions and false statements is unknown.

63. Upon information and belief, Advanced BioHealing's conduct is not limited to New York. Upon information and belief, Advanced BioHealing has made various communications regarding the Apligraf Recall in several other states including Florida, Michigan, and Virginia.

ADVANCED BIOHEALING HAS NOT CEASED ITS WRONGFUL CONDUCT

64. As discussed, despite its representation that it had ceased disseminating communications regarding the Apligraf Recall and Apligraf, Advanced BioHealing has continued disseminating communications regarding the Apligraf Recall and Apligraf.

65. Advanced BioHealing's actions have caused great strain in our relationships with our valued customers.

66. As a result Advanced BioHealing's false advertising claims; OI has likely suffered, and will continue to suffer, substantial harm. Advanced BioHealing has sent the Advanced BioHealing Communication directly to OI's customers and potential customers and Advanced BioHealing is likely to continue to send the same or similar communications to OI's customers and potential customers.

67. Advanced BioHealing's conduct has interfered with the Apligraf Recall. Further, Advanced BioHealing's conduct has likely damaged the Apligraf Brand name and reputation. If Advanced BioHealing's false advertising campaign is permitted to proceed now, the injury to the Apligraf Brand name and reputation will be even more substantial.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed at Canton, MA, this 22nd day of January, 2008.

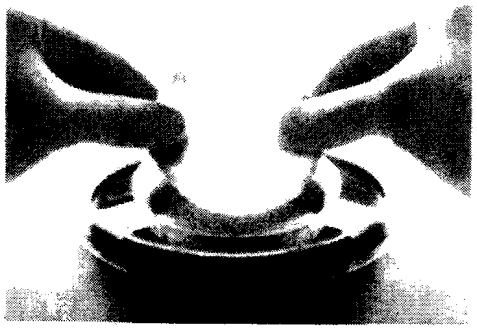
Patrick Bilbo

Exhibit 1

Apligraf hope for healing even the most resistant wounds

- What is Apligraf®?
  - What Wounds Does Apligraf® Treat?
  - How Apligraf® Works
  - How does Apligraf® Compare?
  - How is Apligraf® Applied?
  - After Care/What to Expect?
  - Safety Information
- Find Apligraf®
- Insurance Coverage
- Wound Facts and Prevention
- Read/Share Healing Stories
- Contact Us
- Support and Resources
- Tell a Friend

What is Apligraf®?



After Care/ What to Expect?

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What happens after Apligraf® is applied?
Once Apligraf® is applied, your doctor or nurse will give you instructions to follow while your wound is healing.

Be careful not to disturb your wound or get it wet during the first week of healing.

Within the first week you may have a follow-up visit with your doctor to check the healing progress.

After that your doctor may schedule weekly follow-up visits until your wound is healed. It is very important to keep your follow-up visits and to follow your doctor's directions carefully.

Follow your doctor or nurse's advice on how to improve and maintain your health in order to prevent your sore from coming back.

If you experience any signs of infection, such as tenderness to the touch, redness, pain, heat, and/or swelling, contact your doctor immediately.

FIND APLIGRAF® *at a Wound Care Center near You*

Help Us Understand You Better

■ **TAKE A SURVEY**

Special instructions for patients with diabetic foot sores: One of the most important ways that you can help ensure success is to keep your weight off your feet while your sore is healing. To do this your doctor may advise you to use a wheelchair, crutches or a specially made protective shoe during the first several weeks after Apligraf® is applied. Once your sore has healed, your doctor will also probably want you to wear special footwear to relieve pressure on the newly healed wound.

Special instructions for patients with venous leg sores: Apligraf® is used together with compression therapy, and your doctor will instruct you to wear compression bandages until your sore is healed and possibly afterward. Your doctor may also want you to keep your leg raised as much a possible during the day and to use pillows or cushions to keep your leg slightly raised while you are sleeping. Follow all of your doctor's directions carefully.

Remember too that while Apligraf® can heal your foot or leg sore, it is not a treatment for diabetes or the health condition that caused it to occur in the first place.

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Apligraf

hope for healing even the most stubborn wounds

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  - How Apligraf® Works
  - How does Apligraf® Compare?
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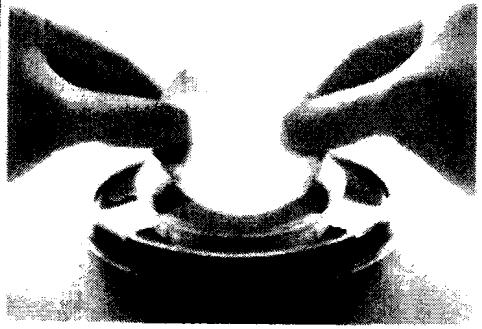
What is Apligraf ?



How does Apligraf® Compare?

Apligraf® heals 30–50% more foot or leg sores, in 1/3 less time than conventional wound care [3,4]

- FIND APLIGRAF® *at a Wound Care Center near You*

Increase Text Size Decrease Text Size

Apligraf® is:

- ***FDA Approved:***
  Apligraf® is an FDA approved product that has been evaluated in multiple controlled clinical studies and is proven to be effective, safe, and to accelerate healing. Many wound care products cannot make such claims.

- ***Superior healing compared to basic wound care:***
  Apligraf® heals more wounds (30% to 50% more) and heals them faster (in 1/3 less time).

- ***Active vs. passive wound healing:***
  Many wound therapies are designed to passively manage the

Help Us Understand You Better

■ **TAKE A SURVEY**

wound. Apligraf® plays a more active role in stimulating the skin to repair itself. Apligraf® delivers the ingredients such as growth factors, cells, and proteins directly to the wound.

- ***A living therapy similar to our own skin:***
  Apligraf® is the only living cell based therapy, containing two different types of skin cells, and is close in structure to natural human skin.

- ***Easy:***
  Apligraf® typically requires no daily maintenance. Dressings are usually changed once a week by your doctor or nurse, depending on your wound type.

References:

3. Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen.* 1999;7:201-207.

4. Veves A, Falanga V, et al. Graftskin, a human skin equivalent, is effective in management of non-infected neuropathic diabetic foot ulcers. *Diabetes Care.* 2001;24:290-295

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Apligraf hope for healing even the most [illegible]

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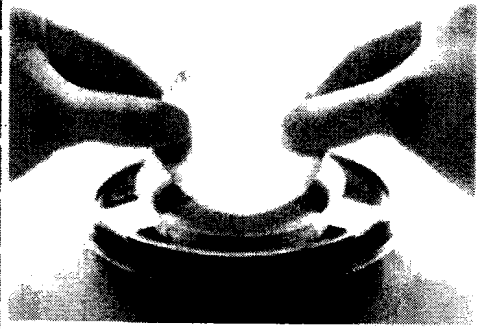

How is Apligraf® Applied?

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Healing sores as quickly as possible

Apligraf® is a living product that must be ordered by your doctor. It may be applied in a hospital, in a Wound Care Center (a medical center specializing in treating non-healing wounds) or in your doctor's office.

First, your doctor prepares your sore for Apligraf® by cleaning it and possibly debriding it (debridement is a treatment involving the removal of dead, damaged or infected tissue from a wound). Then Apligraf® is placed directly on the sore. The wound is then covered with a non-adhesive dressing to keep it moist and to keep Apligraf® in place. The area is then wrapped with other dressings that are changed weekly by the doctor or nurse. The healing process now begins, and improvement of the wound can usually be seen within weeks.

Help Us Understand You Better

■ **TAKE A SURVEY**

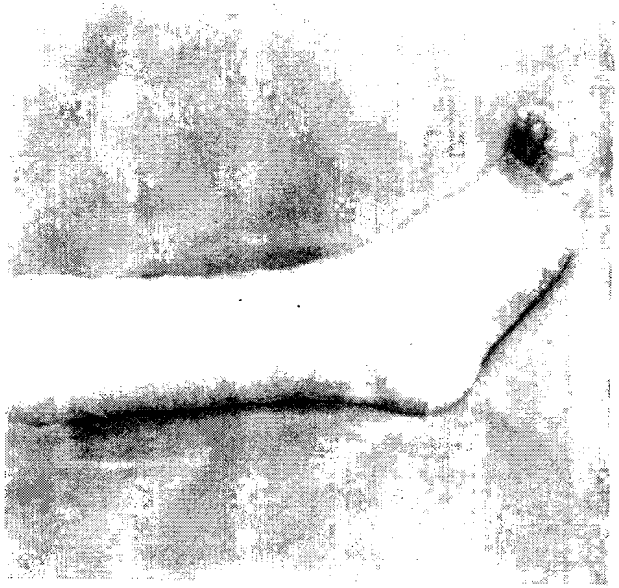
A Wound Care Center is the best place to get treated for your sore, and to find Apligraf®. To find a Wound Care Center near you, click here.

How is Apligraf® applied?

Apligraf® is placed directly on sore

Apligraf® is covered with non-adherent dressing

The area is then wrapped with final dressings



References:

1. Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen.* 1999;7:201-207.

2. Ramsey SD, Newton K, Blough D, et al. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. *Diabetes Care.* 1999;22:382-387.

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Apligraf hope for healing even the most resistant sores

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  - How Apligraf® Works
  - The Science Behind Apligraf®
  - Clinical Experience
  - How does Apligraf® Compare?
  - How is Apligraf® Applied?
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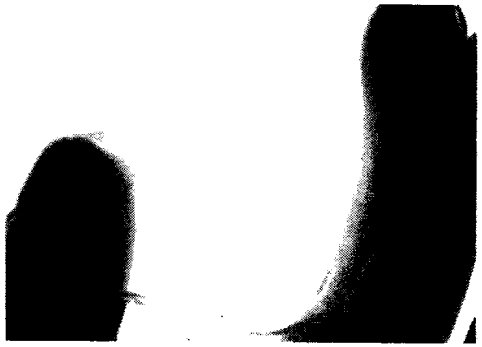

How Apligraf® Works

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The Science Behind Apligraf®

A unique living-cell based therapy available to treat non-healing sores

For patients with diabetic foot sores or venous leg sores, Apligraf® is an advanced biological skin repair therapy, providing hope for healing some of the most persistent non-healing sores.

(More...)

Clinical Experience

Apligraf® heals 30-50% more foot or leg sores, in 1/3 less time than conventional wound care [3,4]

■ FIND APLIGRAF® *at a Wound Care Center near You*

[redacted]

Help Us Understand You Better

■ **TAKE A SURVEY**

A history of healing

Apligraf® was developed and is manufactured by Organogenesis, one of the world's first biotechnology companies, and the world's most important tissue regeneration company. Apligraf® has been used worldwide to heal ulcers for over 10 years. Apligraf® is the first living, cell-based tissue regeneration product, having gained the Food and Drug Administration's approval in 1998.

(More...)

References:

3. Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen.* 1999;7:201-207.

4. Veves A, Falanga V, et al. Graftskin, a human skin equivalent, is effective in management of non-infected neuropathic diabetic foot ulcers. *Diabetes Care.* 2001;24:290-295

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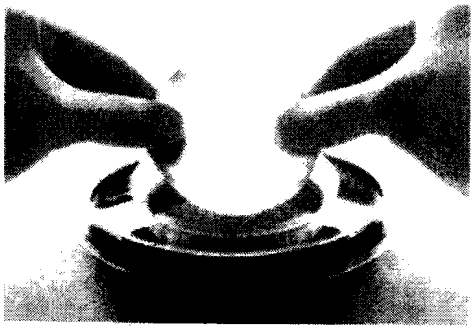
Apligraf hope for healing even the most stubborn sores

- What is Apligraf®?
- What Wounds Does Apligraf® Treat?
- How does Diabetic Foot Ulcer Treatment Work?
- How does Venous Leg Ulcer Treatment Work?
- How Apligraf® Works
- How does Apligraf® Compare?
- How is Apligraf® Applied?
- After Care / What to Expect?
- Safety Information
- Find Apligraf®
- Insurance Coverage
- Wound Facts and Prevention
- Read/Share Healing Stories
- Contact Us
- Support and Resources
- Tell a Friend

What is Apligraf®?



What Wounds Does Apligraf® Treat?

Apligraf® heals 30-50% more foot or leg sores, in 1/3 less time than conventional wound care [3,4]

■ FIND APLIGRAF® at a Wound Care Center near You

▲ Increase Text Size ▼ Decrease Text Size

Hope for healing even the most stubborn sores

Diabetes and problems with circulation can interrupt the skin healing cycle, which in turn can cause non-healing sores and ulcers to develop and linger on.

The two types of non-healing sores treated by Apligraf® are called diabetic foot ulcers and venous leg ulcers. Even if it doesn't hurt, an open sore is a medical emergency. It can lead to life threatening infection, gangrene and, in the case of diabetic foot ulcers, amputation. Venous leg sores can also lead to severe pain.

A non-healing sore is one that is not healing after 3-4 weeks. It may require special medical attention because this kind of wound will not

[redacted]

Help Us Understand You Better

■ **TAKE A SURVEY**

always respond to standard treatments like antibiotics, creams, dressings and debridement (a treatment involving the removal of dead, damaged or infected tissue from a wound).

Beyond being uncomfortable and inconvenient, these types of open sores can seriously impact your quality of life. A stubborn sore can limit your mobility, your day-to-day activities, your independence, and affect your self-esteem.[1]

Learn about Diabetic Foot Sores

Learn about Venous Leg Sores

References:

1. Phillips T, Stanton B, Provan A, et al. A study of the impact of leg ulcers on quality of life: financial, social, and psychologic implications. *J Am Acad Dermatol.* 1994;31:49-53.

2. Capeneart JK. Chronic venous insufficiency: a focus on prevention of venous ulceration. J Wound Ostomy Continence Nurs. 1996;23:227-234.

3. Falanga V. Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. Wound Repair Regen. 1999;7:201-207.

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Apligraf

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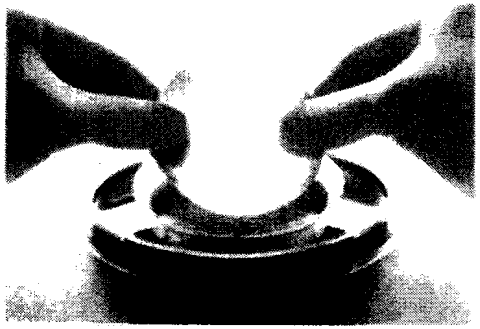
What is Apligraf®?



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Apligraf® is a unique, advanced biological skin repair therapy, and is created from biological ingredients found in healthy human skin. Which explains why it looks like a thin, circular piece of real skin.

It is used to heal sores such as diabetic foot and venous leg ulcers that are not healing after 3-4 weeks, despite treatment with conventional therapies.

When healthy skin gets wounded, the proteins and growth factors in the skin stimulate the body to regenerate new skin. This is the normal wound healing process.[1]
However with certain diseases (like diabetes and circulatory problems), the skin is missing these biological substances, and the healing cycle is broken. This leads to the development of non-healing ulcers and sores.[2,3]

Help Us Understand You Better

■ **TAKE A SURVEY**

Much like your own skin, Apligraf® contains two types of cells – an outer layer of protective skin cells, and an inner layer of cells, both of which contain key healing substances. Apligraf® does not contain certain things in skin such as hair follicles, sweat glands or blood vessels.

Apligraf® is able to help heal and repair chronic sores and regenerate your skin by stimulating the body's natural healing process. It delivers these biological healing substances (fresh cells, nutrients and proteins) directly into the wound, and thus naturally kick starts the healing cycle.

How is Apligraf® different from other wound therapies?

Apligraf® is different because it is NOT a cream, ointment, or traditional wound dressing. It is a biological tissue regeneration therapy made to treat non-healing sores and wounds.

Apligraf® is placed directly on the wound.
The wound is then covered with a non-adhesive dressing to keep it moist and to keep Apligraf® in place. The area is then wrapped with other dressings that are changed weekly by the doctor or nurse. The healing process now begins, and improvement of the wound can usually be seen within weeks.
Many wound therapies, like dressings and antibacterial treatments, are designed to manage a sore until the body heals itself. Apligraf® plays a more active and biological role in stimulating the skin to repair and heal itself. Apligraf® delivers ingredients such as growth factors, cells, nutrients and proteins to the wound directly. And because it is biological, it is natural and well tolerated, with no major reported side effects.

Apligraf® is a prescription product that must be applied by a medical professional. It is not available in pharmacies nor can it be purchased online. To use our locator to find a Wound Care Center with Apligraf® experience nearest you, click here.

Which Wounds Does Apligraf® Treat?

Learn about Diabetic Foot Sores

Learn about Venous Leg Sores

How Apligraf® Works

The Science behind Apligraf®

Clinical Experience

How does Apligraf® Compare?

How is Apligraf® Applied?

After Care/ What to Expect?

Safety Information

References:

1. Kane DP, Krasner D. Wound healing and wound management. In: Krasner D, Kane D, eds. Chronic Wound Care: A Clinical Source Book for Healthcare Professionals. 2nd ed. Wayne, Pa: Health Management Publications Inc; 1997:1-4.

2. Capeheart JK. Chronic venous insufficiency: a focus on prevention of venous ulceration. J Wound Ostomy Continence Nurs. 1996;23:227-234.

3. Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. Wound Repair Regen. 1999;7:201-207.

4. Veves A, Falanga V, et al. Graftskin, a human skin equivalent, is effective in management of non-infected neuropathic diabetic foot ulcers. *Diabetes Care.* 2001:24:290-295.

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Bishop Beater

Exhibit 2

Organogenesis inc.
LIVING TECHNOLOGY
150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf **Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.**

Description of Issue
Apligraf **Lot Number GS0711.20.01.2A** was reported to have contamination in the agarose nutrient medium of some units retained at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition
According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you *have not* applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications
While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 3

Attachments: 20080107053634.pdf

20080107053634.pdf (57 KB)

-----Original Message-----
From: "Andrew Sole" <asole@advancedbiohealing.com>

Date: Tue, 8 Jan 2008 20:30:42
To:undisclosed-recipients:;
Subject: Apligraf Recall Letter

Wound Care Provider,

I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.

A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.

Proprietary cryopreservation process ensures confidence
Dermagraft is cryopreserved to allow long-term maintenance of tissue integrity and cellular viability. Cryopreservation of Dermagraft offers a number of additional product benefits:

- Allows for safety testing prior to shipping and application
- Provides longer shelf life—long-term storage (up to 6 months) when stored at -75°C ± 10°C

There have been no reported immunological responses or rejections from patients that received Dermagraft.

Andrew Sole
Advanced Technolgy Specialist-New York
Advanced BioHealing, Inc.
Direct: 732 991-3610
Email: asole@advancedbiohealing.com
Orders: 1-877-DERMAGRAFT (877-337-6247)

Organogenesis inc.
LIVING TECHNOLOGY
150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf **Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.**

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Clinical Implications
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discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature:_____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 4

Arent Fox

James R. Ravitz
Attorney
202.857.8903 DIRECT
202.857.6395 FAX
ravitz.james@arentfox.com

January 9, 2008

VIA FACSIMILE AND FEDERAL EXPRESS

Mr. Kevin Rakin
Chief Executive Officer
Advanced BioHealing, Inc.
Suite 200
10933 North Torrey Pines Road
La Jolla, CA 92037

Re: Apligraf®

Dear Mr. Rakin,

This firm represents Organogenesis, Inc. (OI). As you are undoubtedly aware, OI is the manufacturer, distributor, and owner of all rights in Apligraf® (Apligraf), an advanced wound healing product. As you also know, OI is currently undertaking a relatively limited recall regarding certain Apligraf units (the Apligraf Recall).

OI recently learned, through numerous reports from physicians that Advanced BioHealing, Inc. (ABH) has sent at least one improper and unlawful written communication regarding Apligraf to a number of physicians. We refer, in particular, to the enclosed electronic mail message (with attachment) that Andrew Sole, an ABH sales representative, sent to an undisclosed number of recipients on January 8, 2008 (the ABH Communication). We assume that the ABH Communication was sent not only to physicians who currently use Apligraf, but also to all physicians who treat wounds. In addition, we have received other similar reports across the country concerning verbal statements by ABH to physicians along the same lines as the ABH Communication.

The ABH Communication is clearly designed to unlawfully denigrate Apligraf, unlawfully promote ABH's product Dermagraft, unlawfully interfere with OI's current and prospective business relationships, and improperly interfere with the Apligraf Recall. This

intention is evidenced by the false, disparaging, and defamatory statements contained in the ABH Communication that we believe violate not only the Federal Food, Drug, and Cosmetic Act, but also various federal and state advertising laws. For instance, the ABH Communication implies that OI is concealing the Apligraf Recall from its customers and failing to conduct the Apligraf Recall in a compliant manner. This is misleading, false and disparaging.

ABH's statements regarding the alleged advantages of cryo-preservation over Apligraf with respect to potential contamination are also misleading and false. In addition to the 1998 Dermagraft recall for endotoxin contamination, the Food and Drug Administration's (FDA) MAUDE database reflects numerous instances of cases where people treated with Dermagraft developed post-implantation complications from the implant. Further, ABH's statement that "Dermagraft goes through 14 day sterility testing by the FDA before it is shipped" is also false. As you undoubtedly are aware, the FDA does not conduct sterility testing or any type of testing for that matter. Such statements are clearly designed and intended to negatively impact OI by misleading physicians into believing that the FDA is involved in the Dermagraft manufacturing process, and that Apligraf, in general, fails to meet FDA standards.

Additionally, ABH's statements that cryo-preservation "allows for safety testing prior to shipping and application" implies that Apligraf is not safety tested prior to release. This is not only false but is disparaging to OI and Apligraf.

Moreover, ABH's actions, which are designed to interfere with OI's ongoing and prospective business relationships, are interfering with OI's ability to conduct the Apligraf Recall. OI is working closely with the FDA to ensure that the Apligraf Recall is conducted in an appropriate and compliant manner. As a result of ABH's actions, however, OI has received several signed recall communications from physicians who did not receive the affected Apligraf unit. Based on information available to us, we believe that those physicians received the recall communication from ABH and were confused as to their responsibilities regarding the Apligraf Recall. Such interference is making it difficult for OI to properly implement and track the effectiveness of the recall. Thus, ABH's actions are significantly negatively impacting the effectiveness of the Apligraf Recall which creates a serious risk to the public health.

Accordingly, OI demands that ABH ***immediately*** cease and desist from interfering with the Apligraf Recall and from making any further false, disparaging, or defamatory statements regarding Apligraf; and that you confirm in writing no later than January 11, 2008, that you will cease your recent activities described herein. We further demand that you provide us with a list of all physicians and wound centers to which the ABH Communication was distributed. In the event that you fail to comply with these demands, OI reserves the right to pursue all legal remedies at its disposal to address ABH's activities. Notwithstanding, OI intends to notify the

Arent Fox

FDA regarding ABH's recent activities so that steps can be taken to minimize the harm that ABH has already caused to the Apligraf Recall from a public health standpoint.

Sincerely,

James R. Ravitz

Enclosure

cc: Mr. Geoff MacKay
Mr. Patrick R. Bilbo
Organogenesis, Inc.
Savalle Sims, Esq.
Arent Fox LLP

Attachments: 20080107053634.pdf

20080107053634.pdf (57 KB)

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There have been no reported immunological responses or rejections from patients that received Dermagraft.

Andrew Sole
Advanced Technolgy Specialist-New York
Advanced BioHealing, Inc.
Direct: 732 991-3610
Email: asole@advancedbiohealing.com
Orders: 1-877-DERMAGRAFT (877-337-6247)

Organogenesis inc.
LIVING TECHNOLOGY
150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

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In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 5

Holland & Knight

Tel 202 955 3000
Fax 202 955 5564

Holland & Knight LLP
2099 Pennsylvania Avenue, N.W., Suite 100
Washington, D.C. 20006-6801
www.hklaw.com

CHARLES D. TOBIN
(202) 419-2539
ctobin@hklaw.com

January 11, 2008

Via Facsimile And U.S. Mail

James R. Ravitz, Esq.
Arent Fox LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

Re: Your letter to Advanced BioHealing, Inc.

Dear Mr. Ravitz:

We are counsel to Advanced BioHealing, Inc. Our client referred to me your January 9, 2008 letter, which you sent on behalf of your client Organogenesis, Inc.

We are reviewing this matter carefully with Advanced BioHealing and will respond to your letter substantively by no later than Friday, January 18.

In the meanwhile please feel free to contact me if there's anything further you would like to discuss.

Very truly yours,

HOLLAND & KNIGHT LLP

Charles D. Tobin

cc: Mr. Kevin Rakin
Michael M. Gaba, Esq.

CDT:hjc # 5049957_v1

Exhibit 6

Arent Fox

January 16, 2008

Savalle C. Sims
Attorney
202.857.8948 DIRECT
202.857.6395 FAX
sims.savalle@arentfox.com

VIA FACSIMILE AND FIRST CLASS MAIL

Charles D. Tobin, Esquire
Holland & Knight
2099 Pennsylvania Avenue, N.W., Suite 100
Washington, D.C. 20004-4801

Re: ***Advanced BioHealing, Inc.***

Dear Chuck:

I write in furtherance of our letter to your client, Advanced BioHealing, Inc. ("Advanced BioHealing") dated January 9, 2008 and this firm's recent discussions with you concerning Advanced BioHealing's recent communications regarding Apligraf and OI's recent Apligraf recall (the "Apligraf Recall").

During our recent discussions, you told us that Advanced BioHealing had ceased disseminating communications regarding the Apligraf Recall ("Advanced BioHealing Communications") while the parties discuss a global resolution of this matter. More specifically, we understood from you that Advanced BioHealing had ceased disseminating the Advanced BioHealing Communications upon receipt of Mr. Ravitz's January 9, 2008 letter to Kevin Rakin, Advanced BioHealing's Chief Executive Officer.

As I shared with you earlier this week, we believe that Advanced BioHealing's dissemination of communications regarding the Apligraf Recall are not limited to communications initiated by Andrew Sole and extend *far* beyond the New York area. As we discussed, Advanced BioHealing's immediate halt of the complained of conduct is of particular importance to OI because Advanced BioHealing's actions are interfering with the Apligraf Recall.

Just today, OI shared with us a troubling communication evidencing that Advanced BioHealing continues to disseminate the Advanced BioHealing Communications despite its representations to the contrary. I refer in particular to the electronic mail message that Carol Gray, an Advanced BioHealing employee sent to one of OI's Apligraf customers located in Richmond, Virginia ***"Re Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft"***. Additionally, an Apligraf customer in Michigan informed OI today that she received the enclosed facsimile on January 10, 2008. At a minimum, the enclosed communications evidence that (1) the Advanced BioHealing Communications are emanating from more than a single employee; (2) the Advanced BioHealing Communications are *not* limited to the New York area;

1050 Connecticut Avenue, NW
Washington, DC 20036-5339
T 202.857.6000 F 202.857.6395

1675 Broadway
New York, NY 10019-5820
T 212.484.3900 F 212.484.3990

555 West Fifth Street, 48th Floor
Los Angeles, CA 90013-1065
T 213.629.7400 F 213.629.7401

Arent Fox

and (3) Advanced BioHealing continues to disseminate the Advanced BioHealing Communications despite its interim agreement not to do so.

OI views these latest developments as particularly egregious given your client's assurances that it had ceased and desisted the complained of conduct. Advanced BioHealing's conduct calls into question the spirit in which it has approached the parties' recent settlement discussions. More importantly, we question with new skepticism Advanced BioHealing's reluctance to provide OI with information that it needs to minimize the harm and confusion that Advanced BioHealing has caused to the Apligraf Recall from a public health standpoint.

Clearly, your client's unwritten assurances are no longer sufficient. Accordingly, we request that Advanced BioHealing provide in writing today assurances that it will cease and desist disseminating statements regarding Apligraf and the Apligraf Recall while the parties' settlement discussions are ongoing.

Sincerely,

Savalle C. Sims

Enclosures
cc: James Ravitz, Esquire
Mr. Geoff MacKay
Mr. Patrick R. Bilbo

From: Limor Glazer-Schwam [mailto:limor.glazerschwam@verizon.net]
Sent: Tuesday, January 15, 2008 11:40 PM
To: Stephen Rowe
Subject: FW: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Note my response to her shameful behavior.

From: Carol Gray [mailto:cgray@advancedbiohealing.com]
Sent: Monday, January 14, 2008 11:39 PM
To: Limor Glazer-Schwam
Subject: RE: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

I would like to send my apology to you. I tried to recall any email that was not received as you can see below.

From: Limor Glazer-Schwam [mailto:limor.glazerschwam@verizon.net]
Sent: Monday, January 14, 2008 10:29 PM
To: Carol Gray
Subject: RE: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Shame on you.

From: Carol Gray [mailto:cgray@advancedbiohealing.com]

Sent: Monday, January 14, 2008 9:10 PM
Subject: Recall: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Carol Gray would like to recall the message, "Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.".

ST MARY MERCY HOSPITAL
A MEMBER OF TRINITY HEALTH
Livonia, MI 48154
P 734.655.4800
www.stmarymercy.org

FAX

Date: 1/16/08 **Pages:** 3

To: Caroline Curtis **From:** Wound Care Center Lorraine

Phone: **Phone:** (734) 655-3800

Fax: (781) 401-1288 **Fax:** (734) 655-3810

Re:

☐ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments**

per our phone conversation, this is the faxed notification we received on 1/10/08.

Thanks
Lorraine

1/16/08: Lorraine Getkin, RN of OC stated she received this fax on Jan 10, 9:50

Vision Statement
To be a truly great hospital, providing comprehensive, coordinated, and compassionate care, every time to everyone

National Committee for Quality Health Care
2004 Award Winner

✓ mary Gilbertsons sheet

Organogenesis Inc.
LIVING TECHNOLOGY
[illegible] Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.

Description of Issue
Apligraf Lot Number GS0711.20.01.2A was reported to have contamination in the agarose nutrient medium of some units retained at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition
According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you *have not* applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications
While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

GS0711.20.02.2A
Lot # of
mary
Gilbertson
12/20/07

discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. **Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).**

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,

Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 7

Sims, Savalle

From: charles.tobin@hklaw.com
Sent: Wednesday, January 16, 2008 7:05 PM
To: Sims, Savalle
Cc: Ravitz, James R.; michael.gaba@hklaw.com
Subject: Advanced BioHealing

Savalle,

We have shared your fax of this evening with our client. We do not believe the dissemination is ongoing, and the material you have provided does not reflect that it is.

To be clear on the timeline:

- In response to your initial letter of January 9, the next day, on January 10, Advanced BioHealing instructed its sales representative Andrew Sole in New York to cease communications about the Apligraf recall.
- My firm was engaged on January 10 to assist Advanced BioHealing in this matter.
- On January 11, Advanced BioHealing instructed its entire sales staff to cease communications about the Apligraf recall.
- On January 14, a followup reminder was given to the entire sales staff.

I had previously offered to provide you with written assurances that Advanced BioHealing has instructed its entire sales staff to refrain from disseminating information about the Apligraf recall. I am doing so now. That instruction has been given, and repeated, as detailed above.

We appreciate the documents you sent with your letter. As you know, we have been asking for two days for Organogenesis to provide specifics instead of vague reports about alleged "ongoing" communications.

The documentation you presented yesterday, as well as the attachments to your letter of today, appear to reflect activity that occurred last week and not current activity. As far as the email you shared tonight, it appears to us that on January 14, this sales rep – instead of disseminating the recall notice, as your letter suggests – was trying to "recall" an earlier email in which she may have disseminated the Apligraf recall notice (her original email is not in the materials that you sent, only correspondence about her effort to "recall" it).

Advanced BioHealing has represented to counsel, and we trust our client's representation, that no further disseminations are being, and that none will be made as we continue to investigate. We are reviewing your settlement proposal. We will continue to work with you in good faith through these issues.

Chuck

Holland + Knight

Charles D. Tobin
Partner
Holland & Knight LLP
2099 Pennsylvania Avenue N.W.
Washington, DC 20006
Main (202) 955-3000
Direct (202) 419-2539

Fax (202) 955-5564
Email ctobin@hklaw.com
www.hklaw.com

Exhibit 8

From: Carol Gray [mailto:cgray@advancedbiohealing.com]
Sent: Monday, January 14, 2008 9:22 AM
Subject: Copy of the Recent Apligraf Recall Letter, Unparalled Safety Profile of Dermagraft.

Keeping You Informed:

Attached is the letter announcing the recent Apligraf recall from Organogenesis. Apligraf recalls have happened many times. (as reported to the FDA and documented on the FDA website).

Dermagraft has an unparalleled safety profile:

Advanced Biohealing, Inc. will not send any Dermagraft to customers, for use on their patients, until the **End of Production- USP Sterility Data** Testing Results are completed (conducted by an independent laboratory):

~end of production **USP Sterility Safety testing is a requirement *before* patient application with Dermagraft.** Dermagraft has a 5 month shelf life.

~end of production **USP Sterility Safety testing results for Apligraf are not obtained until *after* application to patients receiving Apligraf. This may put patients and their providers at risk.**

Apply Dermagraft with confidence! Safety Unparalleled!

Carol Gray
Advanced Technology Specialist
Mobile: 443 306 4762
EMail: cgray@advancedbiohealing.com

Right-click here to download pictures. To help protect your privacy, Outlook prevented automatic download of this picture from the Internet.

Customer Service: 1-877-337-6247

Right-click here to download pictures. To help protect your privacy, Outlook prevented automatic download of this picture from the Internet.

www.Dermagraft.com
www.AdvancedBioHealing.com

Exhibit 9

FDA Enforcement Reports (1991 - present)
1998
FDA ENFORCEMENT REPORT 98-20, 05/20/98

First Match

FDA ENFORCEMENT REPORT 98-20, 05/20/98

FDA ENFORCEMENT REPORT 98-20, 05/20/98

FDA ENFORCEMENT REPORT 98-20, 05/20/98

ENFORCE 05/20/98

RECALLS AND FIELD CORRECTIONS: FOODS -- CLASS I ==========

PRODUCT Basha Foods brand Taboule Salad packaged in 7 ounce and 12 ounce containers and in 5 pound bulk containers. Recall #F-491-8.
CODE All lots containing a three or four digit numeric code which begins with the number 2 or the number 02 and all lot numbers containing a three or four digit code which begins with 3 or 03 and is followed by two numbers ranging from 01 through 11.
MANUFACTURER Basha International Foods, Inc., Hamtramck, Michigan.
RECALLED BY Manufacturer, by visit beginning February 20, 1998. Firm-initiated recall complete. See also FDA press release P98-7, February 20, 1998.
DISTRIBUTION Illinois, Indiana, Michigan.
QUANTITY Approximately 1,250 pounds of taboule were distributed.
REASON Products may be contaminated with Listeria monocytogenes, Salmonella Arizona, Enterobacter cloacae, or Citrobacter freundii.

RECALLS AND FIELD CORRECTIONS: FOODS -- CLASS II ==========

PRODUCT Various bakery products:
1. 9 Inch Lemon Glazed Angelfood Cake, item code 80362, net weight 24 ounce
2. Dillons Signature 6 German Chocolate Brownies, item code 80375, net weight 8 ounce
3. Dillons Signature 6 Caramel Brownies, item Code 80376, net weight 8 ounce
4. 7 Inch German Chocolate Cake, item code 80312, net weight 26 ounce
5. Supreme Chocolate Cake, item code, 80346, net weight 20 ounce
6. 6 German Chocolate Cupcakes, item code 80371, net weight 10 ounce
7. 7 Inch Cherry White Cake, item code 80302, net weight 25 ounce

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS II =========

PRODUCT IVAC MedSystem III Administration Sets, Model 28080E. Recall #Z-549-8. CODE Lot #801548. MANUFACTURER Sistemas Medico Alaris, SA DE C.V., Tijuana, Mexico. RECALLED BY Alaris Medical Systems, Inc., San Diego, California, by telephone and by letter on April 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION California, Florida, Illinois, Indiana, North Carolina, Wisconsin. QUANTITY 500 sets were distributed; firm estimated that 384 sets remained on market at time of recall initiation.
REASON Devices were mis-assembled. The tubing sections were reversed which could result in medication not being delivered and/or blood being drawn from the patients IV site.

PRODUCT << Dermagraft>> brand of Human Dermal Replacement, indicated for use as a temporary wound covering for surgically excised thermal burn wounds: a) << Dermagraft>> -TC; b) << Dermagraft>> . Recall #Z-571/572-8.
CODE Lot numbers: a) 101182 to 102722, non-sequential; b) 101720 to 12783, non-sequential.
MANUFACTURER Advanced Tissue Sciences, Inc. (ATS), La Jolla, California.
RECALLED BY Manufacturer, by letter on March 25, 1998, and by press release on March 30, 1998. Firm-initiated recall ongoing.
DISTRIBUTIO a) Nationwide and international; b) international.
QUANTITY a) 478 units; b) 281 units were distributed.
REASON Devices were manufactured and distributed from fetal bovine serum that did not meet firms specification for endotoxin.

UPDATE Recall #Z-514-8, Model TED 60T Portable Oxygen Monitor (Teledyne Electronic Technologies Analytical Instruments (TET/AI), City of Industry, California), which appeared in the April 22, 1998 Enforcement Report should read: RECALLED BY: Manufacturer, by letter on August 27, 1996. Firm-initiated recall ongoing.

RECALLS AND FIELD CORRECTIONS: DEVICES -- CLASS III ========

PRODUCT Ormco C-Type Release Module, for orthodontic headgear or neck pads:
a) Part No. 715-2020, medium (white) force;
b) Part No. 715-2021, heavy (gray) force.
Recall #Z-563/564-8.
CODE Lot numbers beginning with 7K, 7L, 7M, 8A, 8B, and 8C, covering lots manufactured in October, November and December 1997, and January, February, and March 1998.
MANUFACTURER Sybron Dental Specialties, Inc., Orange, California (responsible firm).
RECALLED BY Ormco Corporation, subsidiary of Sybron Dental Specialties, Inc., Glendora, California, by

Exhibit 10

FDA Enforcement Reports (1991 - present)
2003
Enforcement Report 03-24 June 11, 2003
RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

* First Match

RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II

PRODUCT
a) Pulsar Multiprogrammable Pacemaker, DDD Model 970.
Recall # Z-0875-03;
b) Pulsar Multiprogrammable Pacemaker, DDD Model 972.
Recall # Z-0876-03;
c) Pulsar Multiprogrammable Pacemaker, DDD Model 976.
Recall # Z-0877-03;
d) Pulsar Multiprogrammable Pacemaker, DDDR Model 1270.
Recall # Z-0878-03;
e) Pulsar Multiprogrammable Pacemaker, DDDDR Model 1272.
Recall # Z-0879-03;
f) Pulsar Max Multiprogrammable Pacemaker.
Recall # Z-0880-03;
g) Pulsar Max II Multiprogrammable Pacemaker, DDDR Model 1284. Recall # Z-0881-03;
h) Pulsar Max II Multiprogrammable Pacemaker, DDDR Model 1286. Recall # Z-0882-03;
i) Discovery Multiprogrammable Pacemaker, DDDR Model 1273. Recall # Z-0883-03;
j) Discovery Multiprogrammable Pacemaker, DDDR Model 1274. Recall # Z-0884-03;
k) Discovery II Multiprogrammable Pacemaker, DDD Model 981. Recall # Z-0885-03;
l) Discovery II Multiprogrammable Pacemaker, DDDR Model 1280. Recall # Z-0886-03;
m) Discovery II Multiprogrammable Pacemaker, DDDR Model 1283. Recall # Z-0887-03;
n) Meridian Multiprogrammable Pacemaker, DDDR Model 1275. Recall # Z-0888-03;
o) Meridian Multiprogrammable Pacemaker, DDDR Model 1286. Recall # Z-0889-03;
p) Insignia Plus Multiprogrammable Pacemaker, DDD Model 985. Recall # Z-0890-03;
q) Insignia Plus Multiprogrammable Pacemaker, DDD Model 986. Recall # Z-0891-03;
r) Insignia Plus Multiprogrammable Pacemaker, DDDR Model 1294. Recall # Z-0892-03;
s) Insignia Plus Multiprogrammable Pacemaker, DDDR Model 1295. Recall # Z-0893-03;

t) Insignia Extra Multiprogrammable Pacemaker, DDDR Model 1296. Recall # Z-0894-03;
u) Insignia Extra Multiprogrammable Pacemaker, DDDR Model 1297. Recall # Z-0895-03;
v) Insignia Extra Multiprogrammable Pacemaker, DDDR Model 1298. Recall # Z-0896-03;
w) Contak TR Multiprogrammable Pacemaker, DDDR Model 1241. Recall # Z-0897-03;

CODE
All Serial numbers.
RECALLING FIRM/MANUFACTURER
Guidant Corp-Cpi Division, St Paul, MN, by letter dated May 6, 2003. Firm initiated field correction is ongoing. A May 6, 2003 letter to physicians gave recommendations for avoiding the problem and indicated that software to prevent the problem would be introduced.
REASON
In a rare circumstance (fallback mode when high-rate atrial activity is detected), the battery gauge can over-estimate battery life.
VOLUME OF PRODUCT IN COMMERCE
298,000.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
Neonatal GALT Test Kit, 960 tests per box, packaged under the PerkinElmer Life Sciences Inc. label, catalog No. NG-1100.
Recall # Z-0898-03.
CODE
Lot #115496, Exp. 11/1/03.
RECALLING FIRM/MANUFACTURER
PerkinElmer Life Sciences Inc., Norton, OH, by letter on January 8, 2003. Firm initiated recall is ongoing.
REASON
The Control Cards are incorrectly labeled such that the normal 'N' and abnormal 'A' values are reversed.
VOLUME OF PRODUCT IN COMMERCE
75 kits.
DISTRIBUTION
WI, AR, and MI.

PRODUCT
STA-Compact Hemostasis System with Cap piercing capability.
Recall # Z-0899-03.
CODE
All distributed units with cap piercing option.
RECALLING FIRM/MANUFACTURER
Diagnostica Stago, Inc., Parsippany, NY, by letters on March 5, 2003. Firm initiated recall is ongoing.
REASON
With maintenance of the STA line, the cap-piercing feature may involve potential risk of needle puncture injury.
VOLUME OF PRODUCT IN COMMERCE
137.
DISTRIBUTION

Nationwide.

PRODUCT
Misys Laboratory versions 5.2, 5.23 and 5.3 using Cache Database with linked CPUs. Recall # Z-0900-03.
CODE
Versions 5.2, 5.23 and 5.3.
RECALLING FIRM/MANUFACTURER
Misys Healthcare Systems, Tucson, AZ, by fax on June 26, 2002. Firm initiated recall is complete.
REASON
Customer reports that the processor failed to make patient report updates with two processors running in the LABB area.
VOLUME OF PRODUCT IN COMMERCE
38.
DISTRIBUTION
Nationwide.

PRODUCT
Trident Insert Impactor. Recall # Z-0901-03.
CODE
Catalog Number: 2111-0000.
RECALLING FIRM/MANUFACTURER
Stryker Howmedica Osteonics, Mahwah, NJ, by letters and acknowledgement forms on April 29, 2003. Firm initiated recall is ongoing.
REASON
The ball retaining sleeve on the Trident Insert Impactor can possibly disassemble.
VOLUME OF PRODUCT IN COMMERCE
1,758.
DISTRIBUTION
Internationally.

PRODUCT
a) Hill-Rom brand Affinity three birthing bed. Recall # Z-0902-03;
b) Hill-Rom brand Century+ series bed. Recall # Z-0903-03.
CODE
All units distributed between January 1, 1999 and July 1, 2002.
RECALLING FIRM/MANUFACTURER
Hill-Rom, Inc., Batesville, IN, by letters dated April 24, 2003. Firm initiated recall is ongoing.
REASON
Possible electrical shock hazard, as the power cord grounding pin may break off or become detached.
VOLUME OF PRODUCT IN COMMERCE
12,848.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
<< Dermagraft>> , Human Fibroblast-Derived Dermal Substitute,
2 in. by 3 in. Recall # Z-0904-03.
CODE
Lot 116098.
RECALLING FIRM/MANUFACTURER
Smith and Nephew Wound Management (La Jolla), San Diego, CA, by telephone on or about May 2, 2003, and by

letter on May 7, 2003. Firm initiated recall is ongoing.
REASON
Did not meet finished device specifications for DNA criteria.
VOLUME OF PRODUCT IN COMMERCE
22.
DISTRIBUTION
Nationwide.

PRODUCT
a) Rascal Powered Scooters. Recall # Z-0909-03;
b) Chauffeur Powered Scooters. Recall # Z-0910-03.
CODE
a) Rascal Model Numbers 205, 215, 235, 245, 255, 305, 400.
There are 45,679 serial numbers.
b) Chauffeur Model Numbers are C205, C215, C235, C245, C255,
and C305. There are 45,679 serial numbers involved.
RECALLING FIRM/MANUFACTURER
Electric Mobility Corp., Sewell, NJ, by letter on February 7, 2003, and posted on the firms website on February 14, 2003. Firm initiated recall is ongoing.
REASON
The plastic tires may shatter if the tire is over-inflated and could cause serious injury.
VOLUME OF PRODUCT IN COMMERCE
45,679.
DISTRIBUTION
Nationwide, and Internationally.

PRODUCT
a) Inject 10 Coronary Control Syringe (CCS), 10ml.
Recall # Z-0912-03;
b) Custom Kit. Recall # Z-0913-03.
CODE
a) REF/CAT No.: CCX010, Lot No's. A257336, A258248, A258893, A263340; b) REF/CAT No.: K09-03442C. Lot No. A259058.
RECALLING FIRM/MANUFACTURER
Merit Medical Systems, Inc., South Jordan, UT, by letter on May 16, 2003. Firm initiated recall is ongoing.
REASON
Cracks in the syringe barrels could allow for air aspiration into the syringe barrel.
VOLUME OF PRODUCT IN COMMERCE
7,277 units.
DISTRIBUTION
Nationwide, and France, Malaysia, Taiwan, and Dominican Republic.

PRODUCT
10.5 Fr. Percor STAT-DL intra-Aortic Balloon Catheter Insertion
Kits which contain a Datascope 11.5 Fr. 11" introducer sheaths. These introducer sheaths include a hemostasis valve and a hub which work in conjunction with an introducer dilator. The introducer sheath, after it is dilated by the introducer dilator, is intended to assist the percutaneous insertion of the 10.5 Fr. Intra-Aortic Balloon catheter into the vasculature. Recall # Z-0916-03.
CODE
REF or Order #0684-00-0195-02; P/N #0684-00-0438; Lot #BRV; Exp. Date 03/03/05.
RECALLING FIRM/MANUFACTURER